Draft Legislation: This is a draft item of legislation. This draft has since been made as a UK Statutory Instrument: The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 No. 720

### SCHEDULE 2

## AMENDMENTS TO RETAINED DIRECT EU LEGISLATION

#### Regulation (EC) No 1272/2008

34. After Article 37, insert—

# "Article 37A

#### Procedure where Article 37(1) does not apply

1. This Article applies in relation to substances to which Article 37(1) does not apply.

**2.**—(1) The Agency may produce a proposal for a new or revised mandatory classification and labelling requirement and, where appropriate, specific concentration limits or M-factors.

(2) A Competent Authority may submit to the Agency a proposal for a new or revised mandatory classification and labelling requirement and, where appropriate, specific concentration limits or M-factors.

(3) A proposal under sub-paragraph (1) or (2) must follow the format set out in Part 2 of Annex VI and contain the relevant information provided for in Part 1 of Annex VI.

**3.**—(1) A manufacturer, importer or downstream user of a substance may submit to the Agency a proposal for a mandatory classification of that substance, and, where appropriate, specific concentration limits or M-factors, provided that there is no entry in the UK mandatory classification and labelling list for such substance in relation to the hazard class or differentiation covered by that proposal.

(2) A manufacturer, importer or downstream user who has new information which may lead to a change of the mandatory classification and labelling elements of a substance in the UK mandatory classification and labelling list must submit a proposal to the Agency for a revised classification.

(3) A proposal under subparagraph (1) or (2) must follow the format set out in Part 2 of Annex VI and contain the relevant information provided for in Part 1 of Annex VI.

(4) Where a proposal under subparagraph (1) concerns the mandatory classification and labelling of a substance in accordance with Article 36(3), it must be accompanied by a fee.

**4.** Within 12 months of a proposal being received by or produced by the Agency, the Agency must publish an opinion on the proposal, after giving the parties concerned the opportunity to comment.

5. Where the Agency considers that it is appropriate to impose or revise a mandatory classification and labelling requirement, it must within 12 months submit a recommendation to the Secretary of State to give effect to the opinion, and must send a copy to each of the Devolved Authorities.

6. The Secretary of State must decide whether to accept the recommendation and must publish that decision, together with the reasons for that decision, specifying the date when any new or revised classification is to be included on the UK mandatory classification and labelling list.

7. The Secretary of State's function under paragraph 6 is subject to the consent requirement in Article 53B.

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**8.** Where the Secretary of State's decision is to accept the recommendation, the Agency must without undue delay amend the UK mandatory classification and labelling list in accordance with that decision."